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2D SESSION

H. R. 3883

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of genetically engineered foods.

IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2000

Mr. KUCINICH (for himself, Mr. METCALF, Mr. HINCHEY, Mr. CONYERS, Mr. SANDERS, Ms. WOOLSEY, and Ms. LEE) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of genetically engineered foods.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Genetically Engineered Food Safety Act''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Genetic engineering is an artificial gene transfer process wholly different from traditional breeding.

(2) Genetic engineering can be used to produce new versions of virtually all plant and animal foods. Thus, within a short time, the food supply could consist almost entirely of genetically engineered products.

(3) This conversion from a food supply based on traditionally bred organisms to one based on organisms produced through genetic engineering could be one the most important changes in our food supply in this century.

(4) Genetically engineered foods present new issues of safety that have not been adequately studied.

(5) The Congress has previously required that food additives be analyzed for their safety prior to their placement on the market.

(6) Adding new genes into a food should be considered adding a food additive, thus requiring an analysis of safety factors.

(7) Federal agencies have failed to uphold congressional intent of the Food Additives Amendment of 1958 by allowing genetically engineered foods to be marketed, sold and otherwise used without requiring pre-market safety testing addressing their unique characteristics.

(8) The food additive process gives the Food and Drug Administration discretion in applying the safety factors that are generally recognized as appropriate to evaluate the safety of food and food ingredients.

SEC. 3. FEDERAL DETERMINATION OF SAFETY OF GENETICALLY ENGINEERED FOOD; REGULATION AS FOOD ADDITIVE.

(a) INCLUSION IN DEFINITION OF FOOD ADDITIVE.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) in paragraph (s), by adding after and below subparagraph (6) the following sentence:

''Such term includes the different genetic constructs, proteins of such constructs, vectors, promoters, marker systems, and other appropriate terms that are used or created as a result of the creation of a genetically engineered food (as defined in paragraph (kk)), other than a genetic construct, protein, vector, promoter, or marker system or other appropriate term for which an application under section 505 or 512 has been filed. For purposes of this Act, the term 'genetic food additive' means a genetic construct, protein, vector, promoter, or marker system or other appropriate term that is so included.''; and

(2) by adding at the end the following:

''(kk)(1) The term 'genetically engineered food' means food that contains or was produced with a genetically engineered material.

''(2) The term 'genetically engineered material' means material derived from any part of a genetically engineered organism, without regard to whether the altered molecular or cellular characteristics of the organism are detectable in the material.

''(3) The term 'genetically engineered organism' means—

''(A) an organism that has been altered at the molecular or cellular level by means that are not possible under natural conditions or processes (including but not limited to recombinant DNA and RNA techniques, cell fusion, microencapsulation, macroencapsulation, gene deletion and doubling, introducing a foreign gene, and changing the positions of genes), other than a means consisting exclusively of breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture, and

''(B) an organism made through sexual or asexual reproduction (or both) involving an organism described in clause (A), if possessing any of the altered molecular or cellular characteristics of the organism so described.

''(4) For purposes of subparagraph (1), a food shall be considered to have been produced with a genetically engineered material if the organism from which the food is derived has been injected or otherwise treated with a genetically engineered material (except that the use of manure as a fertilizer for raw agricultural commodities may not be construed to mean that such commodities are produced with a genetically engineered material).''.

(b) PETITION TO ESTABLISH SAFETY.—

(1) DATA IN PETITION.—Section 409(b)(2)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(2)(E)) is amended by adding at the end the following sentence: ''In the case of a genetic food additive, such reports shall include all data that was collected or developed pursuant to the investigations, including data that does not support the claim of safety for use.''.

(2) NOTICES; PUBLIC AVAILABILITY OF INFORMATION.—Section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)) is amended—

(A) by striking ''(5)'' and inserting ''(5)(A)''; and

(B) by adding at the end the following subparagraphs:

''(B) In the case of a genetic food additive, the Secretary, promptly after providing the notice under subparagraph (A), shall make available to the public all reports and data described in paragraph (2)(E) that are contained in the petition involved, and all other information in the petition to the extent that the information is relevant to a determination of the safety for use of the additive. Such notice shall state whether any information in the petition is not being made available to the public because the Secretary has made a determination that the information does not relate to the safety for use of the additive. Any person may petition the Secretary for a reconsideration of such a determination, and if the Secretary finds in favor of such person, the period for public comment under subsection (c)(2)(B) shall be extended accordingly.

''(C) In the case of genetic food additives:

''(i) The Secretary shall maintain and make available to the public through telecommunications a list of petitions that are pending under this subsection and a list of petitions for which regulations under subsection (c)(1)(A) have been established. Such list shall include information on the additives involved, including the source of the additives, and including any information received by the Secretary pursuant to clause (ii).

''(ii) If a regulation is in effect under subsection (c)(1)(A) for a genetic food additive, any person who manufactures such additive for commercial use shall submit to the Secretary a notification of any knowledge of data that relate to the adverse health effects of the additive, when knowledge is acquired by the person after the date on which the regulation took effect. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this clause, including such limits on the responsibilities as the Secretary determines to be appropriate.''.

(3) EFFECTIVE DATE OF REGULATION REGARDING SAFE USE; OPPORTUNITY FOR PUBLIC COMMENT.—Section 409(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(2)) is amended—

(A) by striking ''(2)'' and inserting ''(2)(A)''; and

(B) by adding at the end the following subparagraph:

''(B) In the case of a genetic food additive, an order under paragraph (1)(A) may not be issued before the expiration of the 30-day period beginning on the date on which

the Secretary has under subsection (b)(5) made information available to the public pursuant to a notification under such subsection regarding the petition involved. During such period (or such longer period as the Secretary may designate), the Secretary shall provide interested persons an opportunity to submit to the Secretary comments on the petition. In publishing such notice, the Secretary shall inform the public of such opportunity.''.

(3) CONSIDERATION OF CERTAIN FACTORS.—Section 409(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)) is amended by adding at the end the following paragraph:

''(6) In the case of a genetic food additive, the factors considered by the Secretary regarding safety for use shall include (but not be limited to) the results of the following analyses:

''(A) Allergenicity effects resulting from the added proteins, including proteins not found in the food supply.

''(B) Pleiotropic effects. The Secretary shall require tests to determine the potential for such effects (using molecular characterization, biochemical characterization, mRNA profiling, or other techniques, or as appropriate, combinations of such techniques).

''(C) Appearance of new toxins or increased levels of existing toxins.

''(D) Changes in the functional characteristics of food.

''(E) Changes in the levels of important nutrients.''.

(4) CERTAIN TESTS.—Section 409(c) of the Federal Food, Drug, and Cosmetic Act, as amended by paragraph (3), is amended by adding at the end the following paragraph:

''(7) In the case of genetic food additives:

''(A) If a genetic food additive is a protein from a commonly or severely allergenic food, the Secretary may not establish a regulation under paragraph (1)(A) if the petition under subsection (b)(1) fails to include full reports of investigations that used serum or skin tests (or other advanced techniques) on a sensitive population to determine whether such additive is commonly or severely allergenic.

''(B)(i) If a genetic food additive is a protein that has not undergone the investigations described in subparagraph (A), the Secretary may not establish a regulation under paragraph (1)(A) if the petition under subsection (b)(1) fails to include full re-

ports of investigations that used the best available biochemical and physiological protocols to evaluate whether it is likely that the protein involved is an allergen.

''(ii) For purposes of clause (i), the Secretary shall by regulation determine the best available biochemical and physiological protocols. In carrying out rulemaking under the preceding sentence, the Secretary shall consult with the Director of the National Institutes of Health.''.

(5) PROHIBITED ADDITIVES.—Section 409(c) of the Federal Food, Drug, and Cosmetic Act, as amended by paragraph (4), is amended by adding at the end the following paragraph:

''(8) In the case of a genetic food additive, the Secretary may not establish a regulation under paragraph (1)(A) if—

''(A) the additive is a protein and a report of an investigation finds that the additive is likely to be commonly or severely allergenic;

''(B) the additive is a protein and a report of an investigation that uses a protocol described in paragraph (7)(B) fails to find with reasonable certainty that the additive is unlikely to be an allergen; or

''(C) effective June 1, 2004, a selective marker is used with respect to the additive, the selective marker will remain in the food involved when the food is marketed, and the selective marker inhibits the function of one or more antibiotics.''.

(6) ADDITIONAL PROVISIONS.—Section 409(c) of the Federal Food, Drug, and Cosmetic Act, as amended by paragraph (5), is amended by adding at the end the following paragraph:

''(9)(A) In determining the safety for use of genetic food additives, the Secretary may (directly or through contract) conduct investigations of such additives for purposes of supplementing the information provided to the Secretary pursuant to petitions under subsection (b)(1).

''(B) To provide the Congress with a periodic independent, external review of the Secretary's formulation of the approval process under paragraph (1)(A) that relates to genetic food additives, the Secretary shall enter into an agreement with the Institute of Medicine. Such agreement shall provide that, if the Institute of Medicine has any concerns regarding the approval process, the Institute of Medicine will submit to the Congress a report describing such concerns.

''(C) In the case of genetic food additives, petitions under subsection (b)(1) may not be categorically excluded for purposes of the National Environmental Policy Act.''.

(c) REGULATION ISSUED ON SECRETARY'S INITIATIVE.—Section 409(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(d)) is amended—

(1) by striking ''(d) The Secretary'' and inserting ''(d)(1) Subject to paragraph (2), the Secretary''; and

(2) by adding at the end the following paragraph:

''(2) The provisions of subsections (b) and (c) that expressly reference genetic food additives apply with respect to a regulation proposed by the Secretary under paragraph (1) to the same extent and in the same manner as such provisions apply with respect to a petition filed under subsection (b)(1).''.

(d) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following subsection:

''(h)(1) With respect to a violation of section 301(a), 301(b), or 301(c) involving the adulteration of food by reason of failure to comply with the provisions of section 409 that relate to genetic food additives, any person engaging in such a violation shall be liable to the United States for

a civil penalty in an amount not to exceed $100,000 for each such violation.

''(2) Paragraphs (3) through (5) of subsection (g) apply with respect to a civil penalty under paragraph (1) of this subsection to the same extent and in the same manner as such paragraphs (3) through (5) apply with respect to a civil penalty under paragraph (1) or (2) of subsection (g).''.

(e) RULE OF CONSTRUCTION.—With respect to section 409 of the Federal Food, Drug, and Cosmetic Act as amended by this section, compliance with the provisions of such section 409 that relate to genetic food additives does not constitute an affirmative defense in any cause of action under Federal or State law for personal injury resulting in whole or in part from a genetic food additive.

SEC. 4. USER FEES REGARDING DETERMINATION OF SAFETY OF GENETIC FOOD ADDITIVES.

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by inserting after section 409 the following section:

''USER FEES REGARDING SAFETY OF GENETIC FOOD ADDITIVES

''SEC. 409A. (a) IN GENERAL.—In the case of genetic food additives, the Secretary shall in accordance with this section assess and collect a fee on each petition that is filed under section 409(b)(1). The fee shall be collected

from the person who submits the petition, is due upon submission of the petition, and shall be assessed in an amount determined under subsection (c). This section applies as of the first fiscal year that begins after the date of promulgation of the final rule required in section 5 of the Genetically Engineered Food Safety Act (referred to in this section as the 'first applicable fiscal year').

''(b) PURPOSE OF FEES.—

''(1) IN GENERAL.—The purposes of fees under subsection (a) are as follows:

''(A) To defray increases in the costs of the resources allocated for carrying out section 409 for the first applicable fiscal year over the costs of carrying out such section for the preceding fiscal year, other than increases that are not attributable to the responsibilities of the Secretary with respect to genetic food additives.

''(B) To provide for a program of basic and applied research on the safety of genetic food additives (to be carried out by the Commissioner of Food and Drugs). The program shall address fundamental questions and problems that arise repeatedly during the process of reviewing petitions under section 409(b)(1) with respect to genetic food additives, and shall not

directly support the development of new genetically engineered foods.

''(2) ALLOCATIONS BY SECRETARY.—Of the total fee revenues collected under subsection (a) for a fiscal year, the Secretary shall reserve and expend—

''(A) 95 percent for the purpose described in paragraph (1)(A) and

''(B) 5 percent for the purpose described in paragraph (1)(B).

''(3) CERTAIN PROVISIONS REGARDING INCREASED ADMINISTRATIVE COSTS.—With respect to fees under subsection (a):

''(A) Increases referred to in paragraph (1)(A) include the costs of the Secretary in providing for investigations under section 409(c)(9)(A).

''(B) Increases referred to in paragraph (1)(A) include increases in costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in carrying out section 409 with respect to genetic food additives.

''(c) TOTAL FEE REVENUES; INDIVIDUAL FEE AMOUNTS.—The total fee revenues collected under sub-

section (a) for a fiscal year shall be the amounts appropriated under subsection (f)(2) for such fiscal year. Individual fees shall be assessed by the Secretary on the basis of an estimate by the Secretary of the amount necessary to ensure that the sum of the fees collected for such fiscal year equals the amount so appropriated.

''(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of a fee assessed under subsection (a) if the Secretary finds that the fee to be paid will exceed the anticipated present and future costs incurred by the Secretary in carrying out the purposes described in subsection (b) (which finding may be made by the Secretary using standard costs).

''(e) ASSESSMENT OF FEES.—

''(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after the first applicable fiscal year unless the amount appropriated for salaries and expenses of the Food and Drug Administration for such fiscal year is equal to or greater than the amount appropriated for salaries and expenses of the Food and Drug Administration for the first applicable fiscal year multiplied by the adjustment factor applicable to the fiscal year involved, except that in making determinations under

this paragraph for the fiscal years involved there shall be excluded—

''(A) the amounts appropriated under subsection (f)(2) for the fiscal years involved; and

''(B) the amounts appropriated under section 736(g) for such fiscal years.

''(2) AUTHORITY.—If under paragraph (1) the Secretary does not have authority to assess fees under subsection (a) during a portion of a fiscal year, but does at a later date in such fiscal year have such authority, the Secretary, notwithstanding the due date under such subsection for fees, may assess and collect such fees at any time in such fiscal year, without any modification in the rate of the fees.

''(f) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year lim-

itation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purposes described in paragraph (1) of subsection (b), and the sums are subject to allocations under paragraph (2) of such subsection.

''(2) AUTHORIZATION OF APPROPRIATIONS.—

''(A) FIRST FISCAL YEAR.—For the first applicable fiscal year—

''(i) there is authorized to be appropriated for fees under subsection (a) an amount equal to the amount of increase determined under subsection (b)(1) by the Secretary (which amount shall be published in the Federal Register); and

''(ii) in addition, there is authorized to be appropriated for fees under subsection (a) an amount determined by the Secretary to be necessary to carry out the purpose described in subsection (b)(2) (which amount shall be so published).

''(B) SUBSEQUENT FISCAL YEARS.—For each of the four fiscal years following the first applicable fiscal year—

''(i) there is authorized to be appropriated for fees under subsection (a) an amount equal to the amount that applied under subparagraph (A)(i) for the first applicable fiscal year, except that such amount shall be adjusted under paragraph (3)(A) for the fiscal year involved; and

''(ii) in addition, there is authorized to be appropriated for fees under subsection (a) an amount equal to the amount that applied under subparagraph (A)(ii) for the first applicable fiscal year, except that such amount shall be adjusted under paragraph (3)(B) for the fiscal year involved.

''(3) ADJUSTMENTS.—

''(A) AGENCY COST OF RESOURCES.—For each fiscal year other than the first applicable fiscal year, the amount that applied under paragraph (2)(A)(i) for the first applicable fiscal year shall be multiplied by the adjustment factor (as defined in subsection (i)).

''(B) RESEARCH PROGRAM.—For each fiscal year other than the first applicable fiscal year, the amount that applied under paragraph (2)(A)(ii) for the first applicable fiscal year

shall be adjusted by the Secretary (and as adjusted shall be published in the Federal Register) to reflect the greater of—

''(i) the total percentage change that occurred during the preceding fiscal year in the Consumer Price Index for all urban consumers (all items; U.S. city average); or

''(ii) the total percentage change for such fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

''(4) OFFSET.—Any amount of fees collected for a fiscal year under subsection (a) that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

''(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(h) CONSTRUCTION.—This section may not be construed as requiring that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in carrying out section 409 with respect to genetic food additives be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(i) DEFINITION OF ADJUSTMENT FACTOR.—For purposes of this section, the term 'adjustment factor' applicable to a fiscal year is the lower of—

''(1) the Consumer Price Index for all urban consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April of the first applicable fiscal year; or

''(2) the total of discretionary budget authority provided for programs in categories other than the defense category for the immediately preceding fiscal year (as reported in the Office of Management and Budget sequestration preview report, if available, re-

quired under section 254(c) of the Balanced Budget and Emergency Deficit Control Act of 1985) divided by such budget authority for the first applicable fiscal year (as reported in the Office of Management and Budget final sequestration report submitted for such year).

For purposes of this subsection, the terms 'budget authority' and 'category' have the meaning given such terms in the Balanced Budget and Emergency Deficit Control Act of 1985.''.

SEC. 5. RULEMAKING; EFFECTIVE DATE; PREVIOUSLY UNREGULATED MARKETED ADDITIVES.

(a) RULEMAKING; EFFECTIVE DATE.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall by regulation establish criteria for carrying out section 409 of the Federal Food, Drug, and Cosmetic Act in accordance with the amendments made by section 3, and criteria for carrying out section 409A of such Act (as added by section 4). Such amendments take effect upon the expiration of the 30-day period beginning on the date on which the Secretary promulgates the final rule under the preceding sentence, subject to subsection (b).

(b) PREVIOUSLY UNREGULATED MARKETED ADDITIVES.—

(1) IN GENERAL.—In the case of a genetic food additive (as defined pursuant to the amendments made by section (3)) that in the United States was in commercial use in food as of the day before the date on which the final rule under subsection (a) is promulgated, the amendments made by this Act apply to the additive upon the expiration of the two-year period beginning on the date on which the final rule is promulgated, subject to paragraph (2).

(2) USER FEES.—With respect to a genetic food additive described in paragraph (1), such paragraph does not waive the applicability of section 409A of the Federal Food, Drug, and Cosmetic Act to a petition under section 409(b)(1) of such Act that is filed before the expiration of the two-year period described in such paragraph.

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